



Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-105
Regulation title	Rabies regulations
Action title	Rabies response, prevention and control regulations.
Date this document prepared	3-5-2012

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

HB322 and HB621 of the 2010 General Assembly amended five rabies related sections of the Code of Virginia (§§ 3.2-6521, 3.2-6522, 3.2-6525, 18.2-313.1, and 54.1-3812) and enacted one new section (§3.2-6562.1)(Chapters 182 and 834 of the 2010 Acts of Assembly. In addition, the General Assembly directed the Board of Health to promulgate regulations to implement the provisions of the act. The specific language associated with this directive is “That the Board of Health, in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), shall adopt regulations to implement the provisions of this act. Such regulations shall include a model plan that may be used by localities to comply with the requirements of § 3.2-6562.1 of this act. The model plan shall provide alternatives that reflect variations in local circumstances across the Commonwealth.” The Virginia Department of Health in collaboration with many stakeholder groups, has developed proposed regulatory language to support the implementation of these changes to the *Code of Virginia*. This proposed language addresses the procedure for rabies vaccination exemptions, the development of a rabies response plan by local health departments, recordkeeping associated with rabies clinics and defines common terms that are used in the rabies related sections of the *Code of Virginia*.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

The acronyms that appear in the proposed regulations are as follows: (i) LHD as an abbreviation of local health department and (ii) PEP as an abbreviation for rabies post-exposure prophylactic.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

Chapters 182 and 834 of the 2010 Acts of Assembly, as well as §32.1-12 of the Code of Virginia, authorize the Board to promulgate these regulations. The regulations are necessary to implement the revisions made to certain rabies related sections of the *Code of Virginia* (§§ 3.2-6521, 3.2-6522, 3.2-6525, 18.2-313.1, and 54.1-3812) during the 2010 General Assembly session. In addition, a rabies related section (§ 3.2-6562.1) was added to the *Code of Virginia* during that session. The Board of Health, in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), has been directed to adopt regulations to implement the provisions of the act which became effective on July 1, 2010.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

These regulations are necessary for the protection of public health. Rabies is nearly 100 percent fatal in mammals and is highly endemic in the Commonwealth. It is very important that human and animal exposures are addressed promptly and correctly. Greater detail than is appropriate for the *Code* has been articulated in these regulations to support the implementation of rabies related sections of the *Code* modified and introduced during the 2010 General Assembly session. In addition, the Board of Health has been specifically instructed to develop regulations addressing rabies exemptions and a model rabies response plan. Goals of the proposed language include: (i) to define commonly used terms in the rabies related sections of the *Code of Virginia* to increase the likelihood these terms would be interpreted and applied in a consistent way, (ii) to improve the recordkeeping associated with rabies clinics to increase the likelihood that an animal's vaccinations status can be verified in response to a rabies exposure, (iii) to outline the procedure a veterinarian must use to apply for a rabies vaccination exemption and the role of local authorities in that process, (iv) to offer a model rabies response plan that localities may use to comply with § 3.2-6562.1 of the *Code of Virginia*. The proposed language of these regulations has been developed in cooperation with stakeholders from potentially affected groups such as local health departments, animal control agencies, veterinary associations, humane groups, wildlife agencies, agriculture agencies, the Board of Veterinary Medicine and local government associations. These stakeholders have been engaged to discuss issues such as the entity that grants rabies exemptions and restrictions placed on animals that are exempt as well as the authority local health directors now have to direct animal control officers in the pursuit of their duties in certain circumstances. It is hoped that this

participatory approach has resulted in proposed language that is clearly written, understandable and functional for all those involved in rabies prevention, control and response efforts.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

The provisions in these new regulations address commonly used terms in the rabies related sections of the *Code of Virginia*, the health department's recordkeeping responsibilities associated with rabies clinics, a mechanism whereby dogs and cats may be granted a rabies vaccination exemption and fulfill the requirement, as put forward by the 2010 General Assembly, for the Board of Health to develop a model plan that may be used by localities to comply with the requirements of § 3.2-6562.1.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
2) *the primary advantages and disadvantages to the agency or the Commonwealth; and*
3) *other pertinent matters of interest to the regulated community, government officials, and the public.*

If the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

The main issues associated with the proposed regulatory action include defining common terms used in the *Code of Virginia*, rabies vaccination exemptions, recordkeeping associated with rabies clinics and the development of a model rabies response plan. The primary advantages of these regulations for individual private citizens, veterinarians in private practice and the Commonwealth include: (i) increasing the likelihood that the terms used in the rabies related sections of the *Code of Virginia* will be applied and interpreted in a consistent way in all health districts, (ii) increasing the likelihood that the rabies vaccination status of an animal that was vaccinated as part of a rabies clinic can be verified, (iii) providing a mechanism for granting rabies vaccination exemptions which will allow for a dog or cat owner whose animal is likely to have a life threatening reaction in response to vaccination to be in compliance with local licensing laws, but also contains provisions that will assist local authorities with protecting public health and (iv) improving coordination and communication among local government authorities in response to a rabies exposure event to ensure that residents living in a locality and their animals receive timely and accurate guidance about rabies by creating a model rabies response plan which can be used by local health departments. A potential disadvantage of these regulations includes the time and effort veterinarians in private practice may need to complete the application for vaccination exemption.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements associated with these regulations.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

It is not anticipated that any one locality will bear a disproportionate material impact that would not be experienced by other localities.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

The Virginia Department of Health used a participatory approach in the development of these regulations. Stakeholders from potentially affected groups such as local health departments, animal control agencies, veterinary associations, humane groups, wildlife agencies, agriculture agencies, the Board of Veterinary Medicine and local government associations were engaged in discussing and offering comments associated with issues such as rabies vaccine exemptions, definitions of common terms in the rabies related laws and developing a model plan for rabies exposure response at the local level. No public hearing is planned as part of the development of these regulations.

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>), or by mail, email or fax to Julia Murphy, D.V.M., Virginia Department of Health, 109 Governor St., Richmond, VA 23219, (804) 864-8113 (phone), (804) 864-8139 (fax), Julia.murphy@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last date of the public comment period.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirements creates the anticipated economic impact.

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.</p>	<p>The projected cost is minimal. It is not anticipated that the implementation of these regulations will require additional funding. The additional governmental responsibilities associated with these regulations will be undertaken as part of administrative duties and funded through existing resources.</p>
--	---

<p>Projected cost of the <i>new regulations or changes to existing regulations</i> on localities.</p>	<p>The projected cost is minimal. It is not anticipated that the implementation of these regulations will require additional funding.</p>
<p>Description of the individuals, businesses or other entities likely to be affected by the <i>new regulations or changes to existing regulations</i>.</p>	<p>Veterinary hospitals and private practice veterinarians, particularly those that focus on providing primary care to small animals (i.e., dogs and cats.)</p>
<p>Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>There are over 700 full service veterinary hospitals licensed in Virginia, many of which provide primary care small animal medicine and surgery services. The vast majority, if not all, of these entities are small businesses.</p>
<p>All projected costs of the <i>new regulations or changes to existing regulations</i> for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>It is estimated that 1-2 hours of time may be required for a veterinarian to gather the necessary information to complete a rabies vaccination exemption application. There is likely to be a cost associated with this additional time. Veterinarians may decide to absorb this cost or ask for compensation from the client for all or part of these efforts. It is not anticipated that any real estate development will be necessary in response to these regulations.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Veterinarians will have the opportunity to apply for a rabies vaccination exemption for dogs or cats who they anticipate will have a life threatening reaction to the vaccine, while still allowing their clients to be in compliance with local licensing laws.</p>

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

No alternatives have been considered as The Board of Health, in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code), has been directed to adopt regulations to implement the provisions of this act which will become effective on July 1, 2010.

Regulatory flexibility analysis

Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

No alternatives have been considered as The Board of Health, in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code), has been directed to adopt regulations to implement the provisions of this act which will become effective on July 1, 2010.

The main impact these regulations may have on small businesses would be the impact to veterinarians in private practice and the time and effort veterinarians may need to complete the application for a rabies vaccination exemption. Representatives of veterinarians working in clinical practice participated in the development of the proposed language associated with vaccination exemptions.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

Commenter	Comment	Agency response
pregnancy week by week	we have to prevent rabies	none

The only comment received in response to the NOIRA publication is listed above.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no direct impact expected on families.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact.

Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre-emergency** regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

If a new regulation is being promulgated, use this chart:

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
----------------	-----------------------	--------------------------------------	---

<p>2VAC5-105-10. Definitions</p>	<p>Section defines common terms in the <i>Code of Virginia</i>. None of the terms defined in this section of the proposed regulations are currently defined in <i>Code of Virginia</i> § 3.2-6500, the definitions section associated with Virginia’s comprehensive animal laws.</p>	<p>The definitions section of the <i>Code of Virginia’s</i> comprehensive animal laws (§ 3.2-6500).</p>	<p>All of these or similar terms are used in the <i>Code of Virginia</i> and defining them will increase the likelihood they would be interpreted and applied in a consistent way. The language used in the proposed regulations supports current agency interpretations of these terms as many of these or similar terms are defined in the document “Virginia Guidelines for Rabies Prevention and Control.”</p>
<p>12VAC5-105-20. Rabies clinics</p>	<p>Instructs the local health department to maintain information about rabies clinics approved by the local governing body for 48 months.</p>	<p>§ 3.2-6521, in part, addresses rabies clinics and the recordkeeping responsibilities of other stakeholders involved in those events.</p>	<p>Regulation will increase the likelihood that the vaccination status and/or history of an animal that was vaccinated as part of a clinic can be verified.</p>
<p>12VAC5-105-30. Rabies vaccine exemptions</p>	<p>Provides a mechanism whereby dogs and cats may be exempted from the requirement to be vaccinated for rabies. Regulations in this section have been written to support the new requirement in § 3.2-6521 <i>Code of Virginia</i> that instructs the Board of Health to promulgate regulations to allow an exemption for the requirement articulated in this section for all owners of dogs and cats 4 months of age and older to have them vaccinated for rabies.</p>	<p>§ 3.2-6521 instructs owners of dogs and cats 4 months of age and older to have them currently vaccinated for rabies and also instructs the Board of Health to provide an exemption to this requirement provided that the exemption would not risk public health and safety.</p>	<p>Regulation will allow for a dog or cat owner whose animal is likely to have a life threatening reaction in response to vaccination to be in compliance with local licensing laws, but also contains for provisions that will assist local authorities with protecting public health. Veterinarians may be impacted in regard to the time and effort needed to apply for an exemption. Veterinarians will apply for exemptions via a standardized application available through the local health department. Veterinarians may also be asked to provide additional information. The local health director will then review this information and if there is evidence that vaccinating a dog or cat for rabies would pose a life threatening situation for the animal and exempting this animal from the vaccination requirement would not risk public health and safety, an exemption will be granted and a rabies exemption certificate would be issued by the health department which could be presented in lieu of a rabies vaccination certificate in order for the owner to purchase a dog or cat license.</p>
<p>12VAC5-105-40. Model plan for localities</p>	<p>Provides a model plan that localities can use to improve coordination and communication in responding to rabies related events.</p>	<p>§ 3.2-6521.1 of the <i>Code of Virginia</i> instructs localities adopt a plan to control and respond to the risk of rabies exposure to persons and</p>	<p>This plan may be used by local health departments to improve coordination and communication among local government authorities in response to a rabies exposure event to ensure that residents living in a locality and</p>

		<p>companion animals. This is a new section of the Code for which a model plan is being written as a guide to localities.</p>	<p>their animals receive timely and accurate guidance about rabies. Localities are instructed via this new section of the Code to adopt a plan to control and respond to the risk of rabies exposure to persons and companion animals. This plan is to set forth a procedure that promptly ensures the capture, confinement, isolation, or euthanasia of any animal that has exposed, or poses a risk of exposing, a person or companion animal to rabies. In addition, this plan is to identify the authority and responsibility of the local health department, law-enforcement officers, animal control officers, and any other persons with a duty to control or respond to a risk of rabies exposure. The plan shall provide for law-enforcement officers, animal control officers, and other persons to report to and be directed by the local health director for such purposes. Local health directors are to take the lead on developing this plan and the time and resources needed for this will depending on the health district's existing rabies response plans. The model plan details the responsibilities associated with rabies exposure response for nurses, environmental health specialists, district health directors, district epidemiologists and animal control officers.</p>
--	--	---	--